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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/619,256	07/14/2003	Timo Kalevi Korpela	Korpela 1	6902

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EXAMINER	
KHANNA, HEMANT	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 06/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/619,256	KORPELA ET AL.	
	Examiner	Art Unit	
	Hemant Khanna	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 July 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-16* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-4, and 6-7, drawn to a bioactive peptide to prevent or treat bacterial infections, classified in class 424, subclass 190.1.

   II. Claim 5, drawn to a peptide inhibitor against pathogenic Escherichia coli, classified in class 514, subclass 17.

   III. Claim 8, drawn to an antimicrobial peptide inhibiting polymerization of Dr. haemagglutinin, classified in class 514, subclass 16.

   IV. Claims 9-14, drawn to a method to treat bacterial infections by administering to the patient a therapeutically amount of bioactive peptide, classified in class 435, subclass 7.2.

   V. Claims 15-16, drawn to an inhibitor molecule, classified in class 514, subclass 99.

2. The inventions are independent or distinct, each from the other because:

Inventions Group I and Group II are directed to related products. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the claims drawn to a bioactive peptide do not overlap the scope of the claims drawn to a peptide inhibitor as evidenced by the different sequences and

functions of the claimed inventions. The bioactive peptide, based on the sequence of XTXTYY, has a structure distinct from the structure of the peptide inhibitor, which is based on the sequence TXTYTZ. Further, the bioactive peptide can be used in materially different process of producing antibodies against such proteins, while the peptide inhibitor may be used in the screening of inhibitors against pathogenic Escherichia coli strains.. Therefore, groups I and II are distinct.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

3. Inventions Group I and Group III are directed to related products. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the claims drawn to a bioactive peptide do not overlap the scope of the claims drawn to an antimicrobial peptide as evidenced by the different sequences and functions of the claimed inventions. The bioactive peptide, based on the sequence of XTXTYY, has a structure distinct from the structure of the antimicrobial peptide, which is based on the sequence TTGTTKL. Further, the bioactive peptide can be used in materially different process of producing antibodies against such proteins, while the

antimicrobial peptide is used in inhibiting the polymerization of haemagglutinin.. Therefore, groups I and III are distinct.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

4. Inventions Group I-II and Group IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the product can be used in a materially different process that is distinct from its use in treating a patient with bacterial infection. The bioactive peptide of Group I can be used to produce antibodies against such peptides for use in diagnostics, or the peptide inhibitor of Group II may be used in the screening of inhibitors against pathogenic Escherichia coli strains. Therefore, Groups I-II and IV are distinct.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

5. Inventions Group I-II and Group V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be

shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h).. In the instant case, the product can be used in a materially different process that is distinct from its use in preventing the polymerization of bacterial protein units. The bioactive peptide of Group I can be used to produce antibodies against such peptides for use in diagnostics, or the peptide inhibitor of Group II may be used in the screening of inhibitors against pathogenic Escherichia coli strains. Further, the process of Group V can be practiced with a materially different product involving pyranosides that interact with molecular chaperones to disrupt the polymerization of bacterial polymerization units. Therefore, groups I-II and V are distinct.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

6. Inventions Group II and Group III are directed to related products. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the claims drawn to a peptide inhibitor do not overlap the scope of an antimicrobial peptide in both sequence and function. The peptide inhibitor, based on the

sequence of TXTYTZ, has a structure distinct from the structure of the antimicrobial peptide, which is based on the sequence TTGTTKL. Further, the peptide inhibitor of Group II can be used in materially different process of screening inhibitors against pathogenic Escherichia coli strains, while the antimicrobial peptide of Group III is used in inhibiting the polymerization of haemagglutinin.. Therefore, groups II and III are distinct.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

7. Inventions Group III and Group IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h).. In the instant case, the product can be used in a materially different process that is distinct from its use in treating a patient with bacterial infection. The antimicrobial peptide of Group III can be used to inhibit the polymerization of haemagglutinin. Therefore, groups III and IV are distinct.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

8. Inventions Group III and Group V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the process of Group V can be practiced with a materially different product involving pyranosides that interact with molecular chaperones to disrupt the polymerization of bacterial polymerization units that are materially different from the antimicrobial peptides of Group III. Therefore, groups III and V are distinct.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

9. Should either of Group I, II or III be elected, a further election of species is required. Claims 2-4, 5, and 8 are generic. In Group I, claim 2 is drawn to the following disclosed patentably distinct species: Yersinia and E. coli. The species are independent or distinct because they are drawn to different genus's of gram-negative bacteria carrying different genomes encoding for pathogenicity. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species of gram-negative bacteria, even though this requirement is traversed.

10. In Group I, claim 3 is drawn to the following disclosed patentably distinct species: the amino acid sequence XTXTYY wherein X is any amino acid and Y is a hydrophobic amino acid. Claim 4 is drawn to the following disclosed patentably distinct species: the amino acid sequence XTXTYY wherein X is any amino acid and Y is either leucine or valine. The species are independent or distinct because they are drawn to different sequences having different chemical structures. The search for the above species is not co-extensive particularly with regard to the non-patent literature search. Thus, it would be an undue burden to examine all the species in one application. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species of amino acid sequence with completely defined variables "X" and "Y". In essence, all of the variables should be defined by the elected species even though this requirement is traversed.

11. In Group II, claim 5 is drawn to the following disclosed patentably distinct species: the amino acid sequence TXTYTZ wherein T is threonine, X is selected from a group consisting of alanine and glycine, Y is selected from a group consisting of alanine, threonine, and valine and Z is selected from a group consisting of isoleucine and valine. The species are independent or distinct because they are drawn to different sequences having different chemical structures. The search for the above species is not co-extensive particularly with regard to the non-patent literature search. Thus, it would be an undue burden to examine all the species in one application. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species of amino acid sequence with completely defined variables "X", "Y" and "Z". In essence, all of the

variables should be defined by the elected species even though this requirement is traversed.

12. In Group III, claim 8 is drawn to the following disclosed patentably distinct species: the amino acid sequences GTTGTTKL, TTGTTKL and TTKL. The species are independent or distinct because they are drawn to different sequences having different chemical structures. The search for the above species is not co-extensive particularly with regard to the non-patent literature search. Thus, it would be an undue burden to examine all the species in one application. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species of amino acid sequence even though this requirement is traversed.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Notice of Possible Rejoinder

13. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

14. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hemant Khanna whose telephone number is (571) 272-9045. The examiner can normally be reached on Monday through Friday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ANISH GUPTA
PRIMARY EXAMINER

Hemant Khanna